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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/460,920	12/14/1999	BETH ANNE PIPER	LA0046A	3115

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EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/460,920	PIPER, BETH ANNE	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37, 45-54, 58-60, 71-73, and 75-79, now claims 1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37, 45-54, 58-60, 71-73, and 75-79, now claims 1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *A-G*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

The examiner for the instant application has changed. The current examiner assigned to this application is Amy A. Lewis.

Claims 37, 45-54, 58-60, 71-73, and 75-79 are presented for examination. Previous indication of allowable claims, in the Notice of Allowability mailed 11 February 2003, has been *withdrawn* upon reconsideration of the claims.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 48, which depends form claim 37, contains a broader dosage range for metformin (125-750mg) than is in the original independent claim, which recites a dosage range for metformin of 160-750mg.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37, 45-54, 58-60, 71-73, and 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcomb (US Patent No. 6,011,049) in view of Bauer et al. (US Patent No. 5,258,185).

Whitcomb teaches a combination of a glitazone antidiabetic agent and a biguanidine antidiabetic agent for administration in a method of treating diabetes and improving glycemic control (abstract). The reference teaches administration of 0.25-250mg/day of a sulfonylurea and 300-2000 mg/day of a biguanide, citing glyburide and metformin as the preferred sulfonylurea and biguanide, respectively, which overlaps the instantly claimed dosages and dosage ratios (see: col. 4, lines 45-63; claims 1-3, 7-10, 14-16). Regarding claim 54, Whitcomb also teaches that the diabetic patients administered the treatment regimen had fasting plasma glucose levels greater than 200 mg/dL and HbA1c greater than 9% (see: col. 12, Table 2 and col. 16 lines 17-19).

Whitcomb does not teach particle size of glyburide.

Bauer et al. teaches pharmaceutical formulations of glibenclamide (also known as glyburide) rapidly releasing the active substance for the treatment of diabetes (abstract). The reference teaches that the preparations having micronized glibenclamide, with a mean particle size of ±5 μm, showed improved drug release and bioavailability (col. 2, lines 17-22). The mean particle size of ±5 μm overlaps the instantly claimed particle size range of 2-60 μm. Bauer et al. does not teach co-administration with metformin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use glyburide with a particle size of ±5 μm in the method of

Whitcomb. The skilled artisan would have been motivated to use glyburide with a particle size of ±5 μm, having been taught by the prior art (Bauer et al.) that it has improved drug release and bioavailability. The person of ordinary skill in the art would have had a reasonable expectation of success in treating a diabetic with a combination of glyburide and metformin, having been taught by the prior art (Whitcomb) that it is known that administration of the two compositions together in a treatment regimen results in improved glycemic control. Therefore, the invention as a whole would have been prima facie obvious.

Pertinent Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Barelli et al. (US Patent No. 5,922,769) is considered and equivalent teaching to Whitcomb regarding administration of metformin and glibenclamide (a.k.a., glyburide) as combination therapy in type II diabetes.
- Rothe et al. (US Patent No. 3,979,520) is considered an equivalent teaching to Bauer et al. regarding glyburide particle size and administration for treatment in diabetes.

Conclusion

Claims 37, 45-54, 58-60, 71-73, and 75-79 are rejected. No claims are allowed.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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